REMARKS

Introductory Comments:

Claims 13-28 are pending and were examined in the Office Action dated 2 October 2001. All pending claims stand rejected under 35 U.S.C. §112, first paragraph as unpatentable on the basis of lack of sufficient written description. Applicants respectfully submit that the rejection is improper for the following reasons

The Rejection under 35 U.S.C. §112, first paragraph:

Claims 13-28 stand rejected under 35 U.S.C. §112, first paragraph, on the basis of insufficient written description. More particularly, the Office notes that "the claims are broadly directed toward immunization methods employing any antigens." However, the Office assets "the disclosure only describes the preparation of a single peptide antigen having [a particular amino acid sequence, and] the disclosure does not describe the structure and preparation of any other antigens, particularly those taking the form of a glycopeptide, microbial protein, whole pathogen, viral particle or whole, killed viral particle." See Office Action at page 1. On this basis, the Office concludes that the application contains "subject matter which was not described in the specification in such a way as to reasonable convey to [the skilled artisan] that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants respectfully traverse.

The instant rejection is a written description rejection brought under 35 U.S.C. §112, first paragraph. Thus, in order for applicants to satisfy the written description requirement, their specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that applicants had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d at 1116 (Fed. Cir. 1991). In this regard, applicants can show possession of the claimed invention by describing the claimed invention

with all of its limitations, using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.* 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may also be shown in a variety of other ways including description of an actual reduction to practice, that the invention was "ready for patenting," or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Electronics, Inc.* 48 USPQ2d 1641, 1647 (USSC 1998) and *Amgen Inc. v. Chugai Pharmaceutical,* 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). An application specification may show actual reduction to practice by describing testing of the claimed invention.

Since the instant rejection is directed toward claims that have been added by amendment to the continuation application, the basic proscription is against improper introduction of new matter (introduction of information that goes beyond the subject matter originally filed). See *In re Rasmussen*, 211 USPQ 323, 326 (CCPA 1981). As noted in Section 2163 of the Manual of Patent Examining Procedure, "while there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." Applicants have clearly met their burden under Section 112, first paragraph using the above-noted principals, and the instant rejection is thus improper.

Applicants' specification describes the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that applicants had possession of the claimed invention at the time the application was originally filed. For example, applicants draw the Office's attention to the disclosure provided at page 5, line 11 through page 9, line 24. At page 5, lines 11-19, applicants disclose that "one or more immunogenic peptides or proteins are attached to carrier particles ... delivered to cells ... whereupon a measurable immune response is induced." See applicants' claim 13. At page 9, lines 2-19, applicants disclose that "various particle acceleration devices are known and the choice of one over another is not

critical ... current devices employ an explosive, electric or gaseous discharge to propel the coated particles." See applicants' claims 14 and 15. At page 7, lines 11-25, applicants disclose "the immunogenic peptide is attached to particles that are sufficiently small ... high density metal particles of 0.5-5 microns in size are preferred ... most preferred are amorphous gold particles of 0.5-3 microns in size ... [and] gold spherical particles may also be satisfactorily used." See applicants' claims 16 and 17.

At page 5, line 20 through page 6, line 31, applicants disclose "the immunogenic peptide is intended to encompass any biological molecule that has as all or part of its structure an amino acid chain of sufficient length and suitable sequence to induce an immune response" (see applicants' claims 24-26), "this is specifically intended to encompass molecules generally known as peptides" (see applicants' claims 18-20), "polypeptides and proteins" (see applicants' claims 22 and 23), "as well as molecules that include peptide, polypeptide or protein portions in their structure such as glycopeptides" (see applicants' claim 21). At page 7, lines 4-10, applicants disclose that "the peptide sequence can derive, for example, from viral, fungal, animal, plant, or microbial protein." See applicants' claim 23.

At page 7, line 26 through page 8, line 11, applicants disclose "the peptide molecules can be attached to the carrier particles either by simply mixing ... or by chemically coupling the peptide to the carrier particles." See applicants' claim 27. At page 14, lines 5-30, applicants disclose working examples wherein a peptide of 9 amino acid residues in length (the influenza NP peptide TYQRTRALV) and a peptide of 15 amino acid residues in length (the HIV gp120 peptide) were coated onto carrier particles using the methods of the present invention. See applicant' claims 19 and 20. At page 20, lines 22-32, applicants disclose the manufacture and use of carrier particles coated with whole, killed influenza virus particles. See applicants' claims 24-26.

Finally, at page 12, line 14 through page 13, line 34, applicants disclose that the methods of the present invention are used to induce a humoral or a cytotoxic immune response in any living animal including mammalian animals. See applicants' claim 28.

Accordingly, applicants' specification does describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that applicants had possession of the claimed invention as at their initial filing date. As demonstrated above, applicants can demonstrate possession of their claimed invention by pointing out original specification language describing the claimed invention with all of its limitations, particularly by showing *in haec verba* support for all of the recited claim limitations. All claim limitations added by the Preliminary Amendment submitted with this continuation application thus enjoy support in the specification through express, implicit, or inherent disclosure, and applicants are clearly in compliance with the requirements of Section 112, first paragraph.

In addition to the above express written description of all limitations found in claims 13-28, applicants have also provided express working examples of several of their claimed embodiments, thereby further demonstrating their possession of the recited invention by actual reduction to practice. In particular, in Examples 1-4 (pages 14 through 20), applicants demonstrate that delivery of a peptide obtained from an influenza virus using the methods of the present invention produced both measurable cytotoxic and humoral immune response in the immunized mice. In Example 5 (pages 20 through 23), applicants demonstrate that delivery of a whole, killed viral particle (influenza virus) using the methods of the present invention gave 100% protection against lethal flu virus challenge in the immunized mice. Accordingly, applicants have also demonstrated possession by way of their working examples wherein they described the testing of the claimed invention.

For all of the foregoing reasons, then, applicants respectfully submit that they have indeed provided sufficient written description supporting all of the recited features in their

claims 13-28. Accordingly, the rejection of claims 13-28 under 35 U.S.C. §112, first paragraph, is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

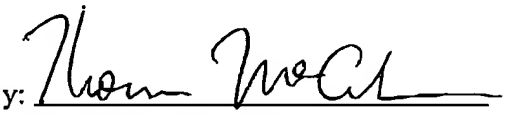
CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. § 112 and define an invention which is novel and nonobvious over the prior art. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

If the Examiner notes any further matters which she believes may be expedited by a telephone interview, he is requested to contact the undersigned attorney in the UK at +44 1865 332 600.

Respectfully submitted,

Date: 2 April 2002

By: 
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